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Standards and FDA's
approach to reuse



Standards related to FDA approach to reuse

- How Standards relate to FDA approach on reuse
- Performance Standards
- Examples of recognized standards



Reuse Policy

- Devices are classified into class I, II, or III
- Must meet existing 510(k) PMA requirements



Procedures

- Use of FDA-Recognized Standards w/a Declaration of Conformity Under Section 5149(c)
- USE of FDA-Recognized Standards w/out a Declaration of Conformity
- Use on Non-Recognized Standards



Performance Standards

- Includes definitions of terms
- Identifies the important characteristics for S&E
- Cites limits or criteria for those variables
- Provides test methods to measure



Examples of Required Standards

Please refer to handout



Problems

Standards Needed





THANK YOU

